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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,769	01/14/2004	Peter J. Littrup	040090-000210US	5491

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EXAMINER

VRETTAKOS, PETER J

ART UNIT PAPER NUMBER

3739

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/757,769	Applicant(s) LITTRUP ET AL	
	Examiner Peter J. Vrettakos	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 23-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/14/05; 1/31/05</u> | 6) <input type="checkbox"/> Other: _____ |

6/24/04 RV 8-19-05

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, drawn to a cryo system, classified in class 606, subclass 20.
- II. Claims 23-30, drawn to a computer readable storage medium, classified in class 606, subclass 20.
- III. Claims 31-33, drawn to a temperature monitoring system, classified in class 374, subclass 10.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because there are numerous patented cryosystems that perform similar acts without the claimed medium. The subcombination has separate utility such as storing data not related to cryosurgery.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the

particulars of the subcombination as claimed because there are numerous patented cryosystems that perform similar acts without the claimed temperature monitoring system. The subcombination has separate utility such as applications not related to cryosurgery.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or III, restriction for examination purposes as indicated is proper.

During a telephone conversation with Patrick Boucher on 8-14-05 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zvuloni et al. (6,706,037).

Zvuloni discloses a cryosurgical system (figure 3) with a plurality of closed end cryoprobes (figure 3, 200) with insulating tips (103), cryogen fluid sources (206, 216), a plurality of flow-control metering valves (208, 218, 232, 205), a compressor (209, 219), electrical wires (204), temperature monitoring (col. 15: 1-8) and a valve controlling computer processor (230,240; col. 14:52-56).

The fluid system is closed loop (see figure 2, arrows in and out of cryoprobe).

Zvuloni discloses Joule-Thomson heat exchangers (200, figure 3) with ports (232) controlled by the processor (col. 14:53-56).

Zvuloni discloses gas (col. 12:48-50) and liquid (inferred in col. 4:61-64; "fluid" includes gas and liquid) cryogen.

Re: cls. 6, 7, 13: avoiding vapor lock is intended use language, which offers no new structure to the claimed invention and therefore no patentable weight to the claim. To address claim language toward adaptations to reduce pressure (etc.), which is arguably intended use as well, the reader is informed that Zvuloni discloses automated and feedback control (of temperature and pressure) via a control unit/computer processor disclosed in col. 7:30-34, as well as col. 14:52 through col. 15:1-8.

Re: cl. 14-15, the claims include intended use language, which holds no patentable weight in system claims. However, the reader is directed to col. 14:57-67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zvuloni in view of Rabin et al. (6,039,730).

Zvuloni discloses no pump.

Rabin discloses an analogous cryosurgical surgical system (figure 4) with a plurality of closed (33) end cryoprobes (1, figure 4), cryogen fluid source ("coolant container", 11), a plurality of flow-control metering valves ("control valves"), a compressor (figure 3, 15 + 31 + 20) **with a pump (31) in fluid communication (13, 9) with the cryoprobes.**

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Zvuloni in view of Rabin by including into the Zvuloni cryotherapy system, a pump. The motivation would be to provide a design expedient common to liquid based cryo systems, which Zvuloni infers several times in the patent through use of the term, "fluid". (Fluid can be a liquid or a gas).

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zvuloni in view of Silver et al. (5,417,072) and further in view of Goldowsky (5,924,975).

Zvuloni discloses no bellows or linear actuator motors.

Silver discloses a cryodevice with bellows 22 (figure 1). Goldowsky discloses a cryodevice with a linear actuator motor (28).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Zvuloni in view of Silver and Goldowsky by including into the Zvuloni cryotherapy system, bellows and a linear actuator motor. The motivation would be to provide a design expedient common to fluid based cryo systems.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zvuloni in view of Gudkin et al. (4,519,389).

Zvuloni discloses no electrode/current generator.

Gudkin discloses an analogous cryoprobe with a heat generator (see title of patent).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Zvuloni in view of Gudkin by including into the Zvuloni cryotherapy system, a thermoelectric cryoprobe. The motivation is found in col. 1 and col. 2 of Gudkin where the benefits of a heat conducting cryoprobe are posited.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zvuloni in view of Stern et al. (5,741,248).

Zvuloni discloses no injections.

Stern discloses injecting cryosensitive agents use a cryoprobe with the needed structure in conjunction with cryosurgery (see Abstract).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Zvuloni in view of Stern by including into the Zvuloni cryotherapy system, a cryoprobe capable of injection. The motivation is to increase the number of potential applications of the Zvuloni system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
August 19, 2005



LINDA C. M. DVORAK
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